IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Syde A. Taheri
Appl. No.	:	10/754,919
Filed	:	January 10, 2004
For	:	TEMPORARY ABSORBABLE VENOUS OCCLUSIVE STENT AND SUPERFICIAL VEIN TREATMENT METHOD
Examiner	:	Sarah K. Webb
Group Art Unit	:	3731

DECLARATION OF MICHAEL MIRIZZI PURSUANT TO 37 CFR 1.132

I, MICHAEL MIRIZZI, declare as follows:

1. I am the Director of Incubation & Research at VNUS Medical Technologies, Inc., assignee of the above-referenced patent application. A true and correct copy of my curriculum vitae is attached as Exhibit 1. From my work history, I am experienced with biodegradable materials, their mechanical properties, and their use in stents and other implanted medical devices.

2. I submit this declaration to discuss the disclosure in U.S. Patent Publication No. 2003/0229366 A1 ("Reggie et al."). The apparatus and method taught by Reggie et al. were developed in connection with medical applications known as "percutaneous in-situ coronary venous arterialization" or "PICVA," and "percutaneous in-situ coronary artery bypass," or "PICAB." (*See* Reggie et al. at ¶ 3.)

3. PICVA and PICAB were invented to be catheter-based technologies for treating heart disease. Specifically, PICVA and PICAB each use a catheter to transform a segment of the coronary venous system into an arterial conduit. In PICVA, a coronary artery is connected to the adjacent vein at one site upstream from the lesion, directing oxygenated blood flow into the vein. The oxygenated blood then travels through the venous system in the reverse direction to perfuse the myocardium. In PICAB, two channels are created between the coronary artery and the adjacent vein, one upstream and the other downstream from the lesion. The blood enters the

upstream channel, flows through the isolated vein to bypass the lesion, and re-enters the healthy segments of the artery through the downstream channel.

4. Based on my knowledge of implanted devices made from biodegradable materials, I believe that the device taught by Reggie et al. would not work for the intended PICVA and PICAB applications if the device were fully biodegradable. In these applications, an occluder is used to block the proximal vein so that arterial blood is not shunted back to the right atrium of the heart. For proper operation, the occluder must have very good vessel wall apposition force so that it does not migrate into the heart under the large arterial pressure acting on the device. I note that there is no teaching, or even suggestion, in Reggie et al. that the occlusion device can provide an adequate apposition force when constructed out of biodegradable materials. Indeed, in my opinion, if the entire Reggie et al. device were constructed from present day biodegradable materials, the device would not achieve the radial strength/vessel apposition force necessary to hold the occluder in place under arterial pressure in a manner that provides total flow occlusion and prevents migration of the occluding device in the blood vessel. All present day biodegradable materials exhibit plastic deformation at significantly lower stress levels than metallic materials. As such, the apposition force for the Reggie et al. device would be orders of magnitude weaker with a biodegradable frame than it would be with the preferred metallic frame taught by Reggie et al. (*See* Reggie et al. at ¶ 15.) Nor does U.S. Patent Publication No. 2003/0040771 A1 ("Hyodoh et al.") include any teaching that addresses this point.

5. Additionally, the PICVA and PICAB applications require the occluding device to quickly route oxygenated blood around the stenosis to perfuse the distal heart tissues. As such, the occluding device must do a good job of occluding immediately. Occlusion by an implant device depends on many factors, including how well tissue grows-in to occlude the vessel, and the durability of the occlusion in preventing recanalization. A fully biodegradable Reggie et al. device would only have a sufficient apposition force to work under arterial pressure if there has been substantial in-growth of tissue connecting the device to the vessel wall. That tissue growth, however, requires time to occur, rendering impossible the quick total occlusion required for the PICVA and PICAB applications in the absence of a strong apposition force provided by the occluding device. Accordingly, there is no teaching, or even suggestion, in Reggie et al. that the

disclosed occlusion device can provide rapid occlusion when constructed out of present day biodegradable materials. Nor does Hyodoh et al. include any teaching that addresses this point.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issuing therefrom.

Respectfully submitted,

Dated: 6/7/06

By: _____
Michael Mirizzi

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EXHIBIT 1

MICHAEL STEPHAN MIRIZZI

6509 Pajaro Ct. San Jose CA 95120 Tel: (H)408-997-8045 (W)408-360-7231

SUMMARY

Demonstrated technical leadership, engineering skill, and management in new product development of medical devices including device and procedure conceptualization, prototyping, detail design, patent prosecution, preclinical testing, verification and validation, clinical studies, manufacturing transfer and product launch.

EDUCATION

CALIFORNIA POLYTECHNIC STATE UNIVERSITY, San Luis Obispo, CA
B.S. Industrial Engineering, June 1991

WORK EXPERIENCE

VNUS MEDICAL TECHNOLOGIES, INC.

Director, Incubation and Research (4/05 to Present)

- I am responsible for incubation and research which spans from developing new ideas and products targeting unmet clinical needs to identifying potential acquisition targets in order to develop strategic product plans for future years. I lead early front-end conception and invention of new clinical therapies for VNUS and spend a significant amount of time performing technical, market and clinical due diligence to create and develop market entry strategies for new target areas. In my role, I recommend for or against further investment in many areas, consider potential license/acquisition strategies for IP, generate new product concepts and evaluate external concepts in an effort to target new project areas with product/revenue potential.
- Created a deal structure "strawman", prior art timeline, and recommended strategy for and participated in acquisition negotiation for company's first IP licensing deal intended to seed new project area for VNUS.
- Responsible for yearly strategic product pipeline planning, budgeting, and goal setting for my department and the greater R&D organization.
- Responsible for hiring and staffing project teams within my group. Currently, I manage and perform reviews for one Project Manager, 5 engineers and one technician.
- Responsible for ensuring intellectual property strategy including domestic and international patent portfolios, invention disclosure, office action review and response for new product concepts.
- I continue to direct project focus for a new product concept using synthetic bioresorbable materials including the alpha-hydroxy acids PLLA, PGA and their co-polymers. This experience includes:
    - Performing research on toxicity, metabolic degradation pathways, and infection rates associated with these polymers.
    - Directing the focus of my project manager to develop novel bioresorbable implants, planning and running animal studies, analyzing histological results, conceptualizing and prototyping device designs, and presenting phase completion updates to Sr. Management.
    - Coordinating analytical testing of polymers which included GPC, DSC, and H1-NMR, ext. to develop bioresorbable raw material specifications.
    - Developing a working knowledge of the mechanical and biochemical properties of biorsorbable materials including PLLA, PDLA, PGA as well as PGLA co-polymers.
    - Ensuring and securing a reliable supply chain for our preferred materials. These activities include understanding and specifying textile fabrication processes (including melt spin extrusion, false-twist texturing, stuffer-box texturing, pin-twist texturing, etc.) as well as identifying potential suppliers.
    - Completing several acute and chronic animal studies to understand bioresorbable device performance including degradation, performance properties, ease of delivery, implant infection and inflammation, and foreign body response.

- Developing a working understanding of the foreign body healing response as it relates to bioresorbable as well as non-bioresrobable biomaterials in the venous vascular bed. This includes analyzing histology sections to determine best modes and guiding team direction based on results.

Program Manager, Research and Development (9/00 to 4/05)

- I was hired to incubate new product concepts in target markets for VNUS. Activities included creatively generating therapeutic concepts for treating venous insufficiency and driving these concepts through feasibility to human use.
- Initially, I invented a new product concept for improving a procedure called ambulatory phlebectomy. Concept consisted of an endovascularly delivered instrument called a "burr" that was rotated and retracted to avulse varicose veins. I managed the concept from concept generation and feasibility all the way to 510k with small team of engineers. Design activities included managing the design history file, filing for and prosecuting patents application, leading FMEA activities, drafting product specs and market needs assessment, as well as writing IFUs, designing packaging and components. I also performed the pre-market marketing, drafted the clinical study physician preference testing plan, completed PPTs and reported results to make a "kill" decision with presentation to Sr. Management.
- Subsequently, conceived of and incubated new product concept for treating perforator veins in the lower limb. Product is called the VNUS RFS product line. Hired 2 consultants on a temporary basis and had two full-time employees to help me incubate product and drive design from concept generation and feasibility to first human use. Completed all design verification activities with team of 4 to obtain 510k clearance and IRB approval for initial human use. Currently, this product line has quarterly sales of ~$350k (~1.4M annual) and is rising.
- Additionally, conceived of a multitude of additional product ideas, performed yearly strategic product pipeline planning, budgeting and goal setting for my project team as well as for the R&D department.
- ANIMAL MODELS: Over 30 studies (Acute and Chronic). Porcine and Caprine studies on radiofrequency occlusion of vessels and surgical resection of vessels, and embolic occlusion of vessels for treating chronic venous insufficiency.

GUIDANT CORPORATION, Compass, Menlo Park, CA (7/99 – 9/00)

Project Group Leader, Neurovascular Venture Startup, Neurovascular Stent Project (1/00 – 9/00)

- In a start up environment, I manage and lead all project activities necessary to complete an IDE filing and start Phase I safety study for the NEUROLINK® Stent and Delivery Catheter as well as the NEUROLINK® Balloon Dilatation Catheter for treatment of ischemic stroke. Two device system indicated for treatment of intracranial and extracranial vertebral artery atherosclerosis.
- Manage a cross organizational team made up of 20+ team members from R&D, Clinical Research, Regulatory Affairs, Manufacturing, and Legal.
- Coordinate design and development efforts and performance testing from prototype to final design. This includes managing Biocompatibility testing, Sterilization Qualification, EtO residual testing, Stent Fatigue Testing, Stent FEA Analysis, and Device Aging and Reliability testing.
- Led team in requirements definition efforts and product Risk Analysis necessary to translate customer needs into engineering requirements.
- ANIMAL MODELS: ~15 studies (Acute). Porcine studies (PTA and PTAS) for treating ischemic stroke.
- HUMAN CADAVER MODELS: ~15 studies

GUIDANT CORPORATION, Vascular Intervention, Santa Clara, CA (11/96-6/99)

Sr. R&D Lead Design Engineer (12/98-6/99)

- Performed early phase customer/clinical research, market research, etc. to develop intravascular therapy for treating ischemic stroke. Provided early design support to the Compass group in stent and delivery system development as well as requirements definition.
- Invented and designed two device therapy (Intracranial Stent System and Balloon Dilatation Catheter) indicated for treating intracranial arterial atherosclerosis. *US patent pending.*

- Organized and completed *in-vitro* and *in-vivo* testing of various prototype designs with Clinical Advisory Board physicians. These studies included both swine models as well as fixed and fresh cadaver models.
- Presented device design and led technical discussion at two Clinical Advisory Board meetings. Physician feedback and success of meetings provided support for continuing device development.
- ANIMAL MODELS: ~5 studies (Acute). Porcine studies (PTA and PTAS) studies for treating ischemic stroke.

Sr. R&D Design Engineer (4/98-11/98)

- Performed early phase customer/clinical needs research, market research, and pathology research to understand the properties and progression of atherosclerosis in Saphenous Vein Grafts (SVGs) used for Coronary Artery Bypass Graft (CABG) surgery in order to define the design path and Design Input necessary to develop a lesion specific intravascular stent therapy for this disease. My activities culminated in the completion of the requirements definition phase of the project and output design needs and specifications for a stainless steel stent. This stent design later became the foundation embodiment for the ACS MULTI-LINK VISOR™ Covered Stent project.
- Invented device for Intravascular Embolic Protection. Embodiment comprised a catheter based Super-Elastic Nickel Titanium (NiTi) basket attached distal to a primary angioplasty balloon. Awarded 2nd place in division wide prototype contest. *US patent pending.*
- Invented stent design, developed machining process, and completed early proof-of-concept activities for the stent implant used on the 2000 launch of the ACS MULTI-LINK TETRA™ Coronary Stent System. This implant design was based on a variable thickness stainless steel tube. *US patent pending.*

Sr. R&D Manufacturing/Process Development Engineer (11/96-3/98)

- Developed stent implant documentation, testing practices, statistical practices, and manufacturing process and quality planning for the ACS MULTI-LINK DUET™ Coronary Stent System project and the SOLO™ Unmounted Stent project. Led the implant manufacturing efforts of the project from the concept phase through regulatory filings to product launch. These development efforts laid the foundation for future stent implant product development efforts. The SOLO/DUET™ Stent was also later selected as the implant for use with the 1999 launch of the ACS MULTI-LINK TRISTAR™ Coronary Stent System.
- Generated protocol strategy and completed all SOLO/DUET™ process qualifications/validations as well as product design verification testing for PMA/S filing.
- Developed laser machining, descale and electropolishing process parameters for the SOLO/DUET™ Stent implant.
- Led two engineer/one consultant team in early design efforts for the SOLO™ Stent Crimping Tool project. *Received US patent #5,974,652.*
- Negotiated and contracted vendors for molding and rapid prototyping crimp tool design iterations.

TARGET THERAPEUTICS, INC., Fremont, CA (1/96-10/96)

Manufacturing (Project) Engineer

- Led manufacturing process development and improvement activities for micro-coil device manufacturing.
- Supported increasing manufacturing capacity by focusing on micro-coil technological process improvements while participating in JIT manufacturing flow process improvements.
- Responsible for assessing technology readiness of existing equipment and fixtures. Developed new technology necessary for transfer of new micro-coil products.
- Project management responsibility for process equipment design, validation, and implementation of a high voltage Arc Discharging Power Supply and next generation servo-system Coil Winders used in manufacturing.

ALCON LABORATORIES, INC., Alcon Surgical, Irvine, CA (8/91-12/95)

Mechanical / Manufacturing Engineer (7/93-12/95)

- Concurrently supported R&D Engineering, CE/TUV/IEC certified, new product development and introduction.
- Supported medical device instrumentation manufacturing by providing mechanical support, operator training, product evaluation, and new tooling design.
- Designed and implemented true JIT Backflush production systems.
- Designed and market released device footswitch accessory; product enhancement for revenue pull through.

Facilities (Project) Engineer (8/91 - 7/93)

- Implemented all manufacturing and warehouse space planning, and layout design projects including layout for two Class 10,000 cleanrooms.
- Implemented all new equipment installations: Environmental Chambers, EMI/RFI room, Scanning Electron Microscope, PCB Surface Mount Technology machine, etc.
- Designed manufacturing Preventative Maintenance Program.

TECHNICAL SKILLS / CERTIFICATIONS / TRAINING

- Applied for and completed 1st Inaugural Emerging Entrepreneur Workshop at Stanford. Selected Intrapreneurial breakout path for focus. Sep. 16-17, 2005.
- Completed patent claim drafting class: Basics of Claim Drafting by Patent Attorney David Lewis. Course hosted by Sc[i]3 Patent and Trademarks PTO library in Sunnyvale on Nov. 1, 2005.
- EIT (Engineer-in-Training): Lic.#XE092047, State of California
- Strong knowledge of Geometric Dimensioning and Tolerancing (GD&T)
- Product Qualification and Validation Experience / Pre-Production Quality Assurance Experience
- Statistical Techniques (DOE, SPC, ANOVA, Inferential, Descriptive)
- Extensive CAD Experience: SolidWorks, AutoCAD, , SmartCAM, CadKey 7
- Visual Basic and Visual Basic for Applications (VBA), HTML / Web Development and Design

PATENTS

US 5,974,652: Method and apparatus for uniformly crimping a stent onto a catheter
US 6,240,615: Method and apparatus for uniformly crimping a stent onto a catheter
US 6,108,886: Method and apparatus for uniformly crimping a stent onto a catheter
US 6,702,802: Catheters with improved transition
US 6,574,851: Stent made by rotational molding or centrifugal casting and method for making the same
US 6,290,710: Embolic protection device
US Patent Pending: Variable Thickness Stent And Method of Manufacture Thereof
US Patent Pending: Cerebral Stent
US 20060052823: Apparatus, material compositions, and methods for permanent occlusion of a hollow anatomical structure
US 20060052822: Apparatus and material composition for permanent occlusion of a hollow anatomical structure
US 20060030849: Methods and apparatus for coagulating and/or constricting hollow anatomical structures
US 20030125759: Method and apparatus for avulsion of varicose veins
Provisional Patent #60/168,192: Digital Medium Music Player & Digital Photograph Player: Abandoned

PUBLICATIONS

Arthur W. Zikorus, Michael S. Mirizzi: Evaluation of Setpoint Temperature and Pullback Speed on Vein Adventitial Temperature During Endovenous Radiofrequency Energy Delivery in an In-Vitro Model. Vascular and Endovascular Surgery, Vol.38 No.2:167-174, 2004.